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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/520,408   | 05/17/2005  | Thomas P. Quinn      | UVMO:023US/10412756 | 2719             |
| 32425  | 7590        | 01/08/2008           | EXAMINER            |                  |
| FULBRIGHT & JAWORSKI L.L.P.<br>600 CONGRESS AVE.<br>SUITE 2400<br>AUSTIN, TX 78701 |             |                      | HOLLERAN, ANNE L    |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1643   |             |                      |                     |                  |
| MAIL DATE  |             | DELIVERY MODE        |                     |                  |
| 01/08/2008   |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 10/520,408      | QUINN ET AL. |
| Examiner                     | Art Unit        |              |
| Anne L. Holleran             | 1643            |              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 October 2007.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
  - 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 and 7-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/ are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION**

*Election/Restrictions*

1. The amendment filed 10/29/2007 is acknowledged.
  
2. Claims 1-20 are pending. Claims 5 and 6, drawn to non-elected inventions, are withdrawn from consideration.

*Claim Rejections/Objections Withdrawn:*

*Objections*

3. The objection to the specification on the grounds that this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) and fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the sequence "KCCYSL" does not have a sequence identifier in the claims is withdrawn in view of the amendment to claim 1.

*Claim Rejections - 35 USC § 102*

4. The rejection of claims 1, 2, and 7-13 under 35 U.S.C. 102(a) as being anticipated by Karasseva (Karasseva, N.G. et al., Journal of Protein Chemistry, 21(4): 287-296, 2002, May) is withdrawn in view of the declaration filed under 37 C.F.R. 1.132 showing that the inventorship of Karasseva is the same as that of the instant invention.

*Claim Rejections - 35 USC § 103*

5. The rejection of claims 1-4, and 7-20 under 35 U.S.C. 103(a) as being unpatentable over Karasseva (supra) in view of Thakur (Thakur, M.L. et al., J. Nuclear Medicine, 41: 107-110,

2000) and further in view of Langer (Langer, M. et al. *Curr. Med. Chem., Anti-Cancer Agents*, 1: 71-93, 2001) is withdrawn in light of the declaration showing that the inventorship of Karasseva is the same as that of the instant invention.

***Claim Rejections Maintained:***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 and 7-20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is that the specification fails to adequately support a genus of peptides that comprise the sequence KCCYSL.

Applicants' arguments have been carefully considered but fail to persuade. Applicants argue that the examiner's rejection is based on three issues;; that applicants have only exemplified a targeting construct of KCCYSL, that the claims encompass peptides up to 100 residues, and the extraneous residues attaches to KCCYSL might block the access of KCCYSL to its target or otherwise hinder its function. Applicants state that the examiner has not properly applied the controlling legal precedent to the fact of the present situation, and that the claims to not lack structural definition, and that one of skill in the art can immediately appreciate that a

given peptide may be lined to other sequences for a variety of purposes. Applicants also provide a declaration demonstrating that KCCYSL may be linked to a radiometal chelator. The arguments provided by applicants as well as the declaration do not address the full scope of the genus which is that the peptides may be quite large in structure compared to the small binding motif, and that the peptide itself, not merely the motif, is what is attached to the agent. Therefore, the genus of peptides has not been adequately described. Applicants may wish to consider an amendment that adds a functional limitation that indicates that the peptide comprising the motif is able to bind to ErbB2. Such an amendment, provided there is support in the specification as originally filed, may obviate the rejection of record.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner

January 6, 2008

  
ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER